IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Boeckl et al. Application No: 10/609,132 Confirmation No: 6677 Filed: June 26, 2003 Title: CONTROLLING THE FLOW OF A POWDER	Group Art Unit: 3721 Examiner: Louis K. Huynh Attorney Docket No: NK.0133.00 December 24, 2008 San Francisco, California 94107

APPEAL BRIEF

VIA ELECTRONIC FILING

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Final Rejection of June 17, 2008 and the Notice of Appeal filed on September 12, 2008, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

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By: Melanie Hitchcock
Melanie Hitchcock

Date: December 24, 2008

(1) *Real Party in Interest*

The real party in interest of the present application is Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.), having a place of business at 201 Industrial Road; San Carlos, California 94070.

(2) *Related Appeals and Interferences*

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) *Status of Claims*

Claims 1-3, 6-22, 24, 31-34, 36-41 and 59-68 are presently pending in the case. Claims 1-3, 6-22, 24, 31-34, 36-41 and 59-68 have been finally rejected. The rejection of each of claims 1-3, 6-22, 24, 31-34, 36-41 and 59-68 is hereby appealed.

(4) *Status of Amendments*

Two Amendments have been filed after Final Rejection. The After-Final Amendment of August 18, 2008 was denied entry in the Advisory Action of August 28, 2008. The After-Final Amendment of September 12, 2008 was promised to be entered for the purpose of appeal in the Advisory Action of October 8, 2008. Accordingly, all amendments except those made in the response of August 18, 2008 have been entered.

(5) *Summary of the Claimed Subject Matter*

As recited in claim 1, discussed on pages 6 through 9 and shown in Figure 1, an apparatus (100) for filling a chamber (125) comprises a hopper (105) adapted to contain

a bulk supply of a powder pharmaceutical formulation (115). The hopper (105) comprises an outlet (120). The apparatus also comprises a vibratable membrane (155) capable of disturbing a medium (145) within the hopper (105), the disturbance of the medium (145) being sufficient to control the flow of powder through the outlet (120). The bulk supply of powder (115) is spaced from the vibratable member (155) when the powder pharmaceutical formulation (115) is present in the hopper (105) and the vibratable member is not vibrating, as discussed on page 10 lines 7-15 and as shown in Figure 1. The chamber (125) may be filled by powder flowing through the outlet (120) and into the chamber (125).

As recited in claim 22, discussed on pages 6 through 9 and shown in Figure 1, an apparatus (100) for filling a chamber (125) comprises a hopper (105) adapted to contain a bulk supply of a powder pharmaceutical formulation (115). The hopper (105) comprises an outlet (120). The apparatus (100) also comprises a vibratable member (135) comprising a membrane (155) positioned in, on, or near the hopper (105) so that the vibratable member (135) is spaced from the powder (115) in the hopper (105) when the vibratable member (135) is not vibrating (as discussed on page 10 lines 7-15 and as shown in Figure 1) and when the hopper (105) contains powder, the vibratable member (135) being capable of fluidizing powder in the hopper (105) that is not in contact with the vibratable member (135). The chamber (125) may be filled with powder flowing through the outlet (120) and into the chamber (125).

As recited in claim 31, discussed on pages 6 through 9 and shown in Figure 1, a method of filling a chamber (125) comprises providing a bulk supply of a powder pharmaceutical formulation (115)in a hopper (105) and providing a separation between the powder and a vibratable membrane (155) when the vibratable membrane (155) is not vibrating, as discussed on page 10 lines 7-15 and shown in Figure 1. The method also comprises disturbing a medium (145) in the hopper (105) by vibrating the vibratable membrane (155) to fluidize the powder, and passing the powder through an outlet (120) and into the chamber (125).

As recited in claim 60, discussed on pages 6 through 10 and shown in Figures 1, 3, 4A and 4B, an apparatus (100) for filling a receptacle (175) comprises a hopper (105) adapted to contain a bulk supply of a powder pharmaceutical formulation (115). The hopper (105) comprises an outlet (120). The apparatus also comprises a vibratable membrane (155) capable of disturbing a medium (145) within the hopper (105), the disturbance of the medium being sufficient to control the flow of powder through the outlet (120). A chamber (125) is movable between a powder collecting position (as shown in Figure 4A) where the chamber (125) collects powder flowing through the outlet (120) and a powder ejecting position (as shown in Figure 4B) where the apparatus (100) can eject powder from the chamber (125) into a receptacle (175). The chamber (125) may be filled by powder flowing through the outlet (120) and into the chamber (125).

As recited in claim 66, discussed on pages 6 through 11 and shown in Figures 5, 6A and 6B, an apparatus (100) for filling a receptacle (125) comprises a hopper (105) adapted to contain a bulk supply of a powder pharmaceutical formulation (115). The hopper (105) comprises an outlet (120). The apparatus also comprises a vibratable membrane (155) capable of disturbing a medium (145) within the hopper (105), the disturbance of the medium (145) being sufficient to control the flow of powder through the outlet (120). The apparatus further comprises a powder vibrating member (250,260) adapted to vibrate the bulk supply of powder while in contact with the powder. The chamber (125) may be filled by powder flowing through the outlet (120) and into the chamber (125).

(6) *Grounds of Rejection to be Reviewed on Appeal*

Appellant requests review of the Examiner's following grounds of rejection:

Claims 1-3 , 6-12, 14, 19-21, 31-34, 36-39, 59, 66 and 67 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,753,302 to Sun et al (hereinafter Sun et al '302).

Claims 1-3, 6, 8, 9, 11-16, 22, 24, 31-34, 36, 37, 39, 40 and 60-65 (note that finally rejected claims 23 and 25-30 have been cancelled) have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 6,168,666 to Sun (hereinafter Sun '666).

Claims 17, 18, 41 and 65 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Sun '666 in view of U.S. Patent 5,858,099 to Sun et al (hereinafter Sun et al '099).

Claim 68 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Sun et al '302.

(7) *Argument*

Appellant believes each of claims 1-3, 6-22, 24, 31-34, 36-41 and 59-68 are improperly rejected and are therefore allowable for the following reasons.

The rejections under 35 U.S.C. §102(b) based on Sun et al '302 are not proper

The Examiner's rejection of claims 1-3 , 6-12, 14, 19-21, 31-34, 36-39, 59, 66 and 67 under 35 U.S.C. §102(b) as being anticipated by Sun et al '302 is improper and should be reversed.

Independent claim 1 and depending claims

Sun et al '302 does not anticipate independent claim 1, for example. For a rejection under 35 U.S.C. §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation.

Claim 1 is not anticipated by Sun et al '302 because Sun et al '302 does not disclose each and every element positively set forth in claim 1. Claim 1 is to an apparatus for filling a chamber, the apparatus comprising, inter alia, a hopper adapted to contain a bulk supply of a powder pharmaceutical formulation, and a vibratable membrane capable of disturbing a medium within the hopper, the disturbance of the medium being sufficient to control the flow of powder through an outlet in the hopper, wherein the bulk supply of powder is spaced from the vibratable member when the powder pharmaceutical formulation is present in the hopper and when the vibratable member is not vibrating, whereby the chamber may be filled by powder flowing through the outlet and into the chamber. These positively recited features are not disclosed by Sun et al '302.

First, Sun et al '302 does not disclose an apparatus for filling a chamber. Sun et al '302 instead discloses an acoustic dispenser (1710) that propels objects from a vibration membrane (1760) towards and for deposition on a substrate (1790). Thus, Sun et al '302 does not disclose a chamber that is filled with a powder, as recited in claim 1. Since this element is missing in Sun et al '302, Sun et al '302 does not anticipate claim 1.

Secondly, Sun et al '302 does not disclose a vibratable membrane that disturbs a medium within a hopper sufficiently to control the flow of powder through an outlet. Instead, Sun et al '302 discloses a vibration membrane (1760) that propels objects towards a substrate (1790). There is no disclosure in Sun et al '302 that the vibration membrane (1760) disturbs a medium within a hopper. Even assuming *arguendo* that there would be at least some disturbance of air with the dispenser of Sun et al '302, there is no disclosure that such disturbance would be sufficient to control the flow of powder through an outlet in the hopper. In contradistinction to the manner of operation of the apparatus of Appellant's claim 1, Sun et al '302 operates by propelling objects, not by disturbing a medium in order to control its flow through an opening. Accordingly, Sun et al '302 fails as an anticipatory reference for this additional reason.

Third, Sun et al '302 does not disclose a vibratable membrane that is spaced from the bulk supply of powder. Instead, the Sun et al '302 discloses objects (1810) that rest on a membrane (1760) and are then propelled from the membrane (1760) towards a substrate (1790), as shown in Figure 2. On page 9 of the Final Office Action of June 17, 2008, the Examiner attempts to explain how the Sun et al '302 reference can be construed to meet this limitation in Appellant's claim 1. The Examiner posits that Sun et al '302 would be capable of meeting the limitations of claim 1 if one were to: (1) rest the objects (1810) on the separation mesh (1770) instead of the vibration membrane (1760) and then (2) turn the entire device upside down so that the objects (1810) could fall onto the substrate (1790). In response the this improper contention, Appellant notes that Sun et al '302 fails to disclose the arrangement envisioned by the Examiner, and the Examiner has improperly distorted the teachings of Sun et al '302. There is no evidence to suggest that Sun et al '302 is capable of being used in the manner suggested. Furthermore, the Examiner's proposition requires making structural modifications to the Sun et al '302 system (e.g. reorientation of the device and placement of the objects in an untaught location) that are not permissible under 35 U.S.C. §102. For at least these reasons, the Examiner's contentions do not show Sun et al '302 to anticipate claim 1.

The Examiner also makes further incorrect contentions on page 9 of the Final Office Action of June 17, 2008. The Examiner improperly characterizes the language in claim 1 as functional language. The language of claim 1 is not functional, but is instead a positive recitation of the structural arrangements of Appellant's invention. This structural language in claim 1 clearly distinguishes the Appellant's device from the Sun et al '302 device which discloses a completely different type of apparatus, i.e. a dispenser and powder propelling device.

Appellant requests reversal of the rejection of claim 1 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 2, 3 and 6-12, 14, and 19-21 which depend from claim 1 and are not anticipated by Sun et al '302 for at least the same reasons as claim 1.

Independent claim 31 and depending claims

Sun et al '302 also does not anticipate independent claim 31. Claim 31 is to a method of filling a chamber, the method comprising, inter alia, providing a bulk supply of a powder pharmaceutical formulation in a hopper and providing a separation between the powder and a vibratable membrane when the vibratable membrane is not vibrating; disturbing a medium in the hopper by vibrating the vibratable membrane to fluidize the powder; and passing the powder through an outlet and into the chamber.

Sun et al '302 does not disclose a method of passing powder through an outlet and into a chamber. Instead, Sun et al '302 discloses propelling objects for deposition on a substrate. There is no chamber disclosed by Sun et al '302. Hence, Sun et al '302 fails to disclose a method of filling a chamber. Furthermore, Sun et al '302 does not disclose providing a separation between a bulk supply of powder and a vibratable membrane when the vibratable membrane is not vibrating. As noted above, Sun et al '302 operates by propelling objects that are in contact with a vibratable membrane towards a substrate. The Examiner argues that "prior to providing the pharmaceutical powder into the hopper (1780) [of Sun et al '302], the vibratable membrane (1760) is not vibrating and the pharmaceutical powder is provided separately into the hopper ... and is not in contact with the vibrating member (1760) before reaching the vibratable membrane ..." (Final Office Action of June 17, 2008, page 10). This argument does not serve to establish Sun et al '302 as an anticipatory reference. For example, note that claim 31 recites "providing a bulk supply of a powder pharmaceutical formulation in a hopper ..." Since claim 31 recites that bulk powder is provided in the hopper, the Examiner's argument about the filling process is misplaced. In addition, the Examiner mischaracterizes the process taught by Sun et al '302. There is no support in Sun et al '302 for the Examiner's supposition that the vibratable membrane is not vibrating when the powder is being introduced into the hopper. Furthermore, gravity dictates that powder in Sun et al '302 will rest on the membrane when it is not vibrating. Accordingly, Sun et al '302 does not anticipate claim 31.

Appellant requests reversal of the rejection of claim 31 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 32-34, 36-39 and 59 which depend from claim 31 and are not anticipated by Sun et al '302 for at least the same reasons as claim 31.

Independent claim 66 and depending claims

In addition, Sun et al '302 does not anticipate independent claim 66. Claim 66 is to an apparatus for filling a receptacle, the apparatus comprising, inter alia, a hopper adapted to contain a bulk supply of a powder pharmaceutical formulation, a vibratable membrane capable of disturbing a medium within the hopper, the disturbance of the medium being sufficient to control the flow of powder through an outlet; and a powder vibrating member adapted to vibrate the bulk supply of powder while in contact with the powder. Sun et al '302 does not disclose ***both*** a vibratable membrane and a powder vibrating member in contact with the powder. Therefore, Sun et al '302 does not anticipate claim 66. Appellant respectfully submits that the Examiner's comments on page 10 of the Final Office Action of June 17, 2008, indicate that the Examiner does not fully appreciate that which is being claimed. The Examiner contends that the two elements recited in Appellant's claim 66 can be satisfied by a single element in Sun et al '302. Appellant maintains that in the absence of a disclosure of each positively recited element, the Sun et al '302 reference does not anticipate claim 66.

Further, for the reasons discussed above, Sun et al '302 fails to disclose an apparatus for filling a chamber. Also as discussed above, Sun et al '302 does not disclose a vibratable membrane that disturbs a medium within a hopper sufficiently to control the flow of powder through an outlet.

Appellant requests reversal of the rejection of claim 66 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claim 67 which depend from claim 66 and is not anticipated by Sun et al '302 for at least the same reasons as claim 66.

The rejections under 35 U.S.C. §102(b) based on Sun '666 are not proper

The Examiner's rejection of claims 1-3, 6, 8, 9, 11-16, 22, 24, 31-34, 36, 37, 39, 40 and 60-65 under 35 U.S.C. §102(b) as being anticipated by Sun '666 is improper and should be reversed.

Independent claim 1 and depending claims

Sun '666 does not anticipate independent claim 1, for example. For a rejection under 35 U.S.C. §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation.

Sun '666 does not anticipate independent claim 1. Claim 1 is to an apparatus for filling a chamber, the apparatus comprising, inter alia, a hopper adapted to contain a bulk supply of a powder pharmaceutical formulation, and a vibratable membrane capable of disturbing a medium within the hopper, the disturbance of the medium being sufficient to control the flow of powder through the outlet, wherein the bulk supply of powder is spaced from the vibratable member when the powder pharmaceutical formulation is present in the hopper and when the vibratable member is not vibrating and whereby the chamber may be filled by powder flowing through an outlet in the hopper and into the chamber. These positively recited features are not disclosed by Sun '666.

First, Sun '666 does not disclose a hopper with an outlet though which powder flows into chamber. Sun '666 instead discloses a bead dispenser (Figure 1) that propels beads towards bead collection zones (BCZ) in a bead transporter chuck (BTC). There is no hopper adapted to contain a bulk supply of powder disclosed in Sun '666. The Examiner posits that the Bead Dispersion Plate (BDP) can be considered to be a hopper (page 5 Final Office Action). However, the BDP of Sun '666 does not disclose an opening through which powder flows. Furthermore, Sun '666 does not disclose an

outlet in a hopper through which powder flows in a controlled manner. Sun '666 discloses the projecting of beads from a mesh to a collection zone and does not disclose the controlling of flow through an outlet.

In addition, Sun '666 does not disclose a vibratable membrane that is spaced from the bulk supply of powder. Instead, in Sun '666 beads are propelled from a mesh (MESH) to a collector (Bead Transporter Chuck BTC). The beads rest on the mesh before they are propelled towards the collector (see Figure 2 of Sun '666). Thus, Sun '666 does not disclose a system where powder is spaced from a membrane when the membrane is not vibrating and does not disclose each and every feature set forth in claim 1. Therefore, Sun '666 does not anticipate claim 1.

The Examiner argues that Sun '666 anticipates claim 1 by construing the claimed vibrating membrane to be the CONE in Sun '666. However, this contention is not proper and still fails to meet the limitations of claim 1. The Examiner's interpretation of the CONE as being the vibratable membrane is improper because one of ordinary skill in the art would recognize the MESH of Sun '666 as part of the vibrating membrane in Sun '666. The MESH of Sun '666 is the part that holds the powder and propels the powder. Thus, the Examiner may not properly ignore the MESH of Sun '666 and the purpose it serves. Since the powder in Sun '666 is not spaced from the MESH when the MESH is not vibrating, Sun '66 does not meet the claim language of claim 1. Furthermore, even assuming *arguendo* the Examiner's contention is valid, the interpretation still fails. The CONE of Sun '666 does not distrub a medium within the hopper, the disturbance of the medium ***being sufficient to control the flow of powder through an outlet***. There is no vibratable membrane in Sun '666 that is responsible for controlling the flow of powder through an outlet. See Figure 2 of Sun '666. For these additional reasons, Sun '666 does not render claim 1 unpatentable.

Appellant requests reversal of the rejection of claim 1 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 2, 3 and 6, 8, 9, and 11-16 which depend from claim 1 and are not anticipated by Sun '666 for at least the same reasons as claim 1.

Independent claim 22 and depending claim

Sun '666 does not anticipate independent claim 22. Claim 22 is to an apparatus for filling a chamber, the apparatus comprising, inter alia, a hopper adapted to contain a bulk supply of a powder pharmaceutical formulation, the hopper comprising an outlet; and a vibratable member comprising a membrane that is spaced from the powder in the hopper when the vibratable member is not vibrating and when the hopper contains powder, the vibratable member being capable of fluidizing the powder in the hopper, whereby the chamber may be filled with powder flowing through the outlet and into the chamber. Sun '666 does not disclose a hopper having an opening as claimed or a vibratable member spaced from powder when the vibratable member is not vibrating, as discussed above. Furthermore, Sun '666 does not disclose a vibratable member comprising a membrane that is capable of fluidizing powder in the hopper that is not in contact with the vibratable member. As noted above, Sun '666 instead discloses a mesh that contacts beads and propels the beads towards a collector, and Sun '666 does not disclose an outlet as claimed. Since Sun '666 does not disclose all that is claimed, it does not anticipate claim 22.

Appellant requests reversal of the rejection of claim 22 under 35 U.S.C. §102(b). In addition, Appelant requests reversal of the rejection of claim 24 which depends from claim 22 and is not anticipated by Sun '666 for at least the same reasons as claim 22.

Independent claim 31 and depending claims

Sun '666 also does not anticipate independent claim 31. Claim 31 is to a method of filling a chamber, the method comprising, inter alia, providing a bulk supply of a powder pharmaceutical formulation in a hopper and providing a separation between the powder and a vibratable membrane when the vibratable membrane is not vibrating; disturbing a medium in the hopper by vibrating the vibratable membrane to fluidize the powder; and passing the powder through an outlet and into the chamber. Sun '666 does not disclose an outlet and the passing of powder through the outlet and into a chamber, as discussed above. Sun '666 also does not disclose providing a separation between the powder and a vibratable membrane. Sun '666 operates by propelling beads that are in contact with a vibratable mesh towards a collector. Thus, Sun '666 does not anticipate claim 31.

Appellant requests reversal of the rejection of claim 31 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 32-34, 36 37, 39 and 40 which depend from claim 31 and are not anticipated by Sun '666 for at least the same reasons as claim 31.

Independent claim 60 and depending claims

In addition, Sun '666 does not anticipate independent claim 60. Claim 60 is to an apparatus for filling a receptacle, the apparatus comprising a hopper adapted to contain a bulk supply of a powder pharmaceutical formulation, the hopper comprising an outlet; a vibratable membrane capable of disturbing a medium within the hopper, the disturbance of the medium being sufficient to control the flow of powder through the outlet, and a chamber movable between a powder collecting position where the chamber collects powder flowing through the outlet and a powder ejecting position where the apparatus can eject powder from the chamber into a receptacle, whereby the chamber may be filled by powder flowing through the outlet and into the chamber. Sun '66 does not disclose a chamber movable between a powder collecting position and a

powder ejecting position, as claimed. In addition, Sun '666 does not disclose an outlet as claimed or the controlling of the flow of powder through an outlet, as claimed and as discussed above. Since Sun '666 does not disclose all that is claimed, it does not anticipate claim 60.

Appellant requests reversal of the rejection of claim 60 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 61-65 which depend from claim 60 and are not anticipated by Sun '666 for at least the same reasons as claim 60.

Other rejections under 35 U.S.C. §102(b) are mute

The Examiner's rejection of claim 22 (note that finally rejected claims 25-30 have been cancelled) under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,826,633 to Parks et al is believed to be moot in view of the September 12, 2008 Amendment After Final Office Action.

The rejections under 35 U.S.C. §103(a) are not proper

Claims 17, 18, 41 and 65

The Examiner's rejection of claims 17, 18, 41 and 65 under 35 U.S.C. §103(a) as being unpatentable over Sun '666 in view of Sun et al '099 is improper and should be reversed.

Sun '666 and Sun et al '099 do not render claims 17, 18, 41 and 65 unpatentable. Claims 17 and 18 depend from claim 1; claim 41 depends from claim 31; and claim 65 depends from claim 60. Claims 1, 31 and 60 are allowable over Sun '666, as discussed above. Sun et al '099 is not relied on by the Examiner to teach that which Sun '666 lacks. Thus, since Sun et al '099 does not make up for the deficiencies of Sun '666, independent claims 1, 31 and 60 are allowable over Sun '666 and Sun et al '099.

As an aside, in contrast with the assertions of the Examiner, Sun et al '099 fails to disclose a rotatable powder transport chuck. Therefore, claims 17, 18, 41 and 65 are allowable over Sun '666 and Sun et al '099 for at least the same reasons as claims 1, 31 and 60. Appellant requests reversal of the rejection of claims 17, 18, 41 and 65 under 35 U.S.C. §103(a).

Claim 68

The Examiner's rejection of claim 68 under 35 U.S.C. §103(a) as being unpatentable over Sun et al '302 is improper and should be reversed.

Sun et al '302 does not render claim 68 unpatentable. Claim 68 depends from claim 66 which is allowable over Sun '302, as discussed above. Since claim 68 depends from an allowable claim, claim 68 is also allowable. Furthermore, claim 68 recites a frequency range that is not taught by Sun et al '302. Since the teachings of Sun et al '302 are used for a different purpose than the invention of claim 68(i.e. the propelling of objects onto a substrate and not the controlling of powder flow through an opening), it would not have been obvious to one having ordinary skill in the art to modify Sun et al '302 as suggested by the Examiner, particularly in the absence of any motivation to do so. Therefore, claim 68 is allowable over Sun et al '302, and Appellant requests reversal of the rejection of under 35 U.S.C. §103(a).

Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: December 24, 2008

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(8) Claims Appendix

1. An apparatus for filling a chamber, the apparatus comprising:

a hopper adapted to contain a bulk supply of a powder pharmaceutical formulation, the hopper comprising an outlet; and

a vibratable membrane capable of disturbing a medium within the hopper, the disturbance of the medium being sufficient to control the flow of powder through the outlet,

wherein the bulk supply of powder is spaced from the vibratable member when the powder pharmaceutical formulation is present in the hopper and the vibratable member is not vibrating and whereby the chamber may be filled by powder flowing through the outlet and into the chamber.

2. An apparatus according to claim 1 wherein the medium comprises a gas.

3. An apparatus according to claim 1 wherein the medium comprises air.

6. An apparatus according to claim 1 wherein the membrane is adapted to vibrate at a frequency selected to fluidize the powder.

7. An apparatus according to claim 1 wherein the membrane is adapted to vibrate at a frequency selected to cause resonance within the container.

8. An apparatus according to claim 1 wherein the vibratable member is adapted to vibrate at a frequency of from about 10 Hz to about 1000 Hz.

9. An apparatus according to claim 1 further comprising a powder vibrating member.

10. An apparatus according to claim 9 wherein the powder vibrating member comprises a member adapted to vibrate in contact with the powder.

11. An apparatus according to claim 9 wherein the powder vibrating member has a longitudinal axis and wherein the powder vibrating member vibrates in a direction parallel to the longitudinal axis.

12. An apparatus according to claim 1 wherein the chamber is a chamber in a receptacle.

13. An apparatus according to claim 12 wherein the receptacle is a blister pack.

14. An apparatus according to claim 12 wherein the receptacle is a capsule.

15. An apparatus according to claim 1 further comprising the chamber and wherein the chamber is adapted to transport the powder to a receptacle.

16. An apparatus according to claim 15 wherein the chamber is a metering chamber.

17. An apparatus according to claim 15 wherein the chamber is in a rotatable member.

18. An apparatus according to claim 17 wherein the rotatable member is rotatable between a powder receiving position and a powder ejecting position.

19. An apparatus according to claim 1 wherein the hopper comprises an enclosure having side walls.

20. An apparatus according to claim 19 wherein the hopper comprises a cover and wherein the vibratable membrane is in proximity to the cover.

21. An apparatus according to claim 19 wherein the hopper comprises a cover and wherein the cover comprises the vibratable membrane.

22. An apparatus for filling a chamber, the apparatus comprising:

a hopper adapted to contain a bulk supply of a powder pharmaceutical formulation, the hopper comprising an outlet; and

a vibratable member comprising a membrane positioned in, on, or near the hopper so that the vibratable member is spaced from the powder in the hopper when the vibratable member is not vibrating and when the hopper contains powder, the vibratable member being capable of fluidizing powder in the hopper that is not in contact with the vibratable member,

whereby the chamber may be filled with powder flowing through the outlet and into the chamber.

24. An apparatus according to claim 22 wherein the membrane is adapted to vibrate at a frequency selected to fluidize the powder.

31. A method of filling a chamber, the method comprising:

providing a bulk supply of a powder pharmaceutical formulation in a hopper and providing a separation between the powder and a vibratable membrane when the vibratable membrane is not vibrating;

disturbing a medium in the hopper by vibrating the vibratable membrane to fluidize the powder; and

passing the powder through an outlet and into the chamber.

32. A method according to claim 31 wherein the medium comprises a gas.

33. A method according to claim 31 wherein the medium comprises air.

34. A method according to claim 31 comprising disturbing the medium by generating vibrations within the medium.

36. A method according to claim 31 wherein the membrane is adapted to vibrate at a frequency selected to fluidize the powder so that the powder will pass through the outlet.

37. A method according to claim 36 wherein the membrane is vibrated at a frequency of from about 10 Hz to about 1000 Hz.

38. A method according to claim 31 further comprising vibrating a member that is in contact with the powder.

39. A method according to claim 31 wherein the chamber comprises a receptacle and further comprising sealing the receptacle.

40. A method according to claim 31 further comprising transferring the powder from the chamber to a receptacle.

41. A method according to claim 31 comprising rotating the chamber from a powder receiving position to a powder ejecting position.

59. A method according to claim 31 further comprising vibrating the bulk supply of powder with a vibratable member in contact with the bulk supply of powder.

60. An apparatus for filling a receptacle, the apparatus comprising:

a hopper adapted to contain a bulk supply of a powder pharmaceutical formulation, the hopper comprising an outlet;

a vibratable membrane capable of disturbing a medium within the hopper, the disturbance of the medium being sufficient to control the flow of powder through the outlet, and

a chamber movable between a powder collecting position where the chamber collects powder flowing through the outlet and a powder ejecting position where the apparatus can eject powder from the chamber into a receptacle,

whereby the chamber may be filled by powder flowing through the outlet and into the chamber.

61. An apparatus according to claim 60 wherein the medium comprises air.

62. An apparatus according to claim 60 wherein the membrane is adapted to vibrate at a frequency selected to fluidize the powder.

63. An apparatus according to claim 60 further comprising a powder vibrating member.

64. An apparatus according to claim 60 wherein the chamber is a metering chamber.

65. An apparatus according to claim 60 wherein the chamber is in a rotatable member.

66. An apparatus for filling a receptacle, the apparatus comprising:

a hopper adapted to contain a bulk supply of a powder pharmaceutical formulation, the hopper comprising an outlet;

a vibratable membrane capable of disturbing a medium within the hopper, the disturbance of the medium being sufficient to control the flow of powder through the outlet; and

a powder vibrating member adapted to vibrate the bulk supply of powder while in contact with the powder,

whereby the chamber may be filled by powder flowing through the outlet and into the chamber.

67. An apparatus according to claim 66 wherein the powder vibrating member has a longitudinal axis and wherein the powder vibrating member vibrates in a direction parallel to the longitudinal axis.

68. An apparatus according to claim 66 wherein the powder vibrating member vibrates at a frequency of from about 1000 Hz to about 180,000 Hz.

(9) Evidence Appendix

none

(10) Related Proceedings Appendix

none